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CONFIRMATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. FILING DATE APPLICATION NO. 09/997,610 11/29/2001 Brian A. Fox 00-96 7590 07/17/2002 Jennifer K. Johnson, J.D. **EXAMINER** ZymoGenetics, Inc. SNEDDEN, SHERIDAN 1201 Eastlake Avenue East Seattle, WA 98102 PAPER NUMBER ART UNIT DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

1,		Application No		Applicant(s)						
		09/997,610		FOX ET AL.						
-	Office Action Summary	Examiner								
		Sheridan K Sne	iden	Art Unit						
	The MAILING DATE of this communication appo		3							
Period fo	• •									
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).										
Status	Despensive to communication(s) filed on									
1) <u>□</u> 2a)□	Responsive to communication(s) filed on This action is FINAL . 2b) \(\times \) This	— · s action is non-f	inal							
	<i>,</i> —			acception on to the m	marita ia					
3)	Since this application is in condition for alloward closed in accordance with the practice under E				nents is					
Disposition	on of Claims									
•	Claim(s) 1-21 is/are pending in the application.									
_	4a) Of the above claim(s) <u>1-5 and 16-21</u> is/are w	vithdrawn from o	consideration.							
· _	Claim(s) is/are allowed.									
	6)⊠ Claim(s) <u>6-15</u> is/are rejected.									
	Claim(s) is/are objected to.									
	Claim(s) are subject to restriction and/or papers	election require	ment.							
· · ·										
· <u> </u>	The specification is objected to by the Examiner.		adda by the Even	in or						
10)	The drawing(s) filed on is/are: a) ☐ accept Applicant may not request that any objection to the	•	-							
11)□ T		= : :	-							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.										
12) The oath or declaration is objected to by the Examiner.										
Priority under 35 U.S.C. §§ 119 and 120										
	Acknowledgment is made of a claim for foreign	priority under 35	5 U.S.C. § 119(a)	-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:										
	1. Certified copies of the priority documents	have been rece	eived.							
:	2. Certified copies of the priority documents have been received in Application No									
:	3. Copies of the certified copies of the priority documents have been received in this National Stage									
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.										
	Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).									
	a) The translation of the foreign language provisional application has been received.									
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.										
Attachment		_								
2) Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s)	4) 5) 6)		(PTO-413) Paper No(s)atent Application (PTO-15						

DETAILED ACTION

Applicant's election of Invention II, Claims 6-15 is acknowledged. Election was made without traverse in Paper No. 6.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 11 of this application. The claim recites "SEQ ID NO: 7," which is not disclosed in the provisional application upon which priority is claimed.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The disclosure is objected to because of the following informalities:

- 1. The reference cited on page 1, line 36 is incomplete. See also page 21, line 3.
- The sequence disclosed on page 18 line 34 is not in compliance with 37 CFR
 1.822 (d) which clearly states that any amino acid sequence shall be listed using the three-letter abbreviation with the first letter as an upper case character

Appropriate correction is required.

Art Unit: 1653

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6, 8, 11, 12 and dependent claims thereto are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The above claims are directed to an isolated nucleic acid encoding a polypeptide of SEQ ID NO: 2, host cells, expression vectors and a method for producing the polypeptide of SEQ ID NO: 2, identified in the specification as Zarcp13. The nucleic acid above is disclosed as have utility in the detection of Zarcp13 gene expression (page 62, line 20), in the production of Zarcp13 polypeptide and as having therapeutic use (page 85, line 21). Of the above uses, none provide a specific or substantial asserted utility or a well established utility. Basic research, such as studying the properties of the claimed product itself or the mechanisms in which the material is involved, such as gene expression, do not constitute specific or substantial utilities. The therapeutic methods disclosed in the specification teach the treatment of unspecified disease or condition. Specifically, the specification merely states that the Zarcp13 nucleic acids may be provided to subjects in need of Zarcp13 treatment. Neither the specification nor the art of record disclose any diseases or conditions caused or exacerbated by Zarcp13. The asserted utility in this case essentially is a method of treating an unspecified, undisclosed disease or condition, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use.

Additionally, the use of the nucleic acid in the method of making a polypeptide that itself has no specific and substantial asserted or well established utility is itself not specific and

Art Unit: 1653

substantial or well establish. The specification as filed does not disclose or provide any evidence that points to an activity for the protein and furthermore there is no art of record that discloses or suggests any activity for the claimed protein. The specification discloses the Zarcp13 polypeptide as having potential use, or that may be evaluated for such potential use, as a modulator of energy balance and cellular metabolic reactions (page 74, line 15); as a antimicrobial (page 77, line 21); as a modulator of calcium ion concentration, muscle contraction, hormone secretion DNA synthesis or cell growth, etc (page77, line 35); as an inducer of platelet aggregation (page 76, line 21); as having therapeutic use thereof (page 83, line 3); and as having an educational use (page 84, line 20). Further experimentation is required to identify a specific and substantial use for the polypeptide as only prophetic uses not yet evaluated are disclosed in the specification. Furthermore, the non-prophetic uses disclosed for the polypeptide, *e.g.* educational purposes, do not show specific utility as it states a general use of all polypeptides.

Page 4

Thus, the claimed polynucleotide encoding protein is not supported by either a specific and substantial asserted utility or a well established utility as to the above because the specification fails to assert any well established utility for the protein and neither the specification as filed nor any art of record disclose or suggest any activity for the protein such that any utility would be well established for the protein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1653

Claims 6, 8, 11, 12 and dependent claims thereto are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because each number of the Markush group recites "comprising." In item (a) the polypeptide "comprises" residues "19-45 of SEQ ID NO: 2," but comprises is open ended and can include residues 1-459 of SEQ ID NO: 2. Similarly, each recited member of (b) through (h) are similarly indefinite because it is not apparent how each member of the Markush group is mutually exclusive one from the other and because each item (a) through (h) overlap each other.

Claim 7 is indefinite as to "moiety" (singular) and the members recited in the Markush group (all plural). In addition, it is unclear in the claim what the common feature of each moiety is or is not supposed to be or have been.

Claim 8 is indefinite as to "portion" as to what is or is not the "a first portion" and the "a second portion." Is "portion " all or only part of items (a) through (g)? In addition, as to the "a second portion," does or does it not include a second or third of "a first portion" as "the second

Art Unit: 1653

Page 6

portion comprising another polypeptide" does not preclude same when "another" is interrupted to mean "additional but not necessarily different" as opposed "different."

Claim 9 is indefinite as to what is or is not a "collagen-like" domain. In addition it is not clear what is or is not a "complement related protein" with regards to both structure and function.

Claim 10 is indefinite regarding overlapping members of the Markush group (See explanation is discussion above, claim 6). See same issue in claim 12.

Claim 11 is indefinite as the nucleotides are not distinct one from the other as ranges overlap.

Claim 12 is objected to because improper Markush language is recited in the claim. The claim should recite "an amino acid sequence selected from the group consisting of." The claim as stated recites a vector that consist of all DNA segments listed (a)-(h) in the claim.

Claims 13-15 are indefinite for being dependent from indefinite claims and do not correct issue of the indefinite claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 6, 8, 10, 11 and dependent claims thereto are rejected under 35 U.S.C. 102(a) as being anticipated by Bridgeman (Accession Number: Z82198). Bridgeman discloses a human nucleotide sequence that is identical to SEQ ID NO: 1 between the base pairs 98 and 1381.

Art Unit: 1653

Thus, the sequence anticipates the nucleic acid molecules consisting of base pairs 179-448 and 137-448 of SEQ ID NO: 1 recited in claim 11. Furthermore, the nucleic acid of Bridgeman would encode for the polypeptide comprising amino acid residues 60-149 and 46-149 of SEQ ID NO: 2 recited in claims 6, 8 and 10. As written, the use of "consisting" in claims 10 and 11 may be interpreted as "open" language. Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bridgeman (Accession Number: Z82198) in view of Lee *et al.* (Biotechnol Prog. 1999). Bridgeman discloses a human nucleotide sequence that is identical to SEQ ID NO: 1 between the base pairs 98 and 1381. This nucleic acid would encode for the polypeptide comprising amino acid residues 60-149 and 46-149 of SEQ ID NO: 2 recited in claim 12. Bridgeman does not teach an expression vector, host cell or method of isolating a polypeptide.

Lee *et al.* teach an expression system comprising of expression vector, secretory enhancer sequence and cultured cells. Lee *et al.* teach the insertion of a polynucleotide into the expression vector. The expression vector contains a secretory enhancer sequence operably linked to the DNA of interest that promotes the secretion of the synthesized protein of interest into the culture

Art Unit: 1653

media. Lee *et al.* additionally teach the introduction of the vector into cultured cells, culturing of the cells and how to produce and isolated the recombinant protein.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to insert the known nucleic acid molecule encoding for the polypeptide comprising amino acids 60-149 and 46-149 of SEQ ID NO: 2 into an expression vector taught by Lee *et al.* (claim 12). The expression vector of Lee *et al.* contains a secretory signal operably linked to the DNA segment of interest (claim 13). It would have been obvious to the person of ordinary skill in the art at the time the invention was made to introduce of the expression vector to a cultured cell and then to utilize that cell in a method of producing and isolating the polypeptide (claims 14 and 15).

The person of ordinary skill in the art would have been motivated, and reasonably would have expected success, to insert the known nucleic acid into an expression vector comprising a secretory signal because such expression vectors are used in the art to produce recombinant protein (Lee *et al.*). Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the

Art Unit: 1653

organization where this application or proceeding is assigned are (703) 746-3975 for regular communications and (703) 746-3975 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS

July 15, 2002

CHRISTOPHER S. F. LOW SUPERVISORY PATENT EXAMINER Page 9

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14368. .14452
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'note="MIR repeat: matches 49.

5071. .15188
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/note="match: GSS: Em:B56592"
/note="match: 1072"
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14616. .15060
/note="match: GSS: E
14868. .15040
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/note="MIR repeat:
13398. .13698
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/note="MIR repeat:
14061. .14367
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/note="MIR repeat:
14597. .15201
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/note="match: STS:
13331. .13397
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                                                                         /note="12 rep
8914. or
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corresponding to the overlapping clone, as we submit sequences with only a small overlap as described above.

This sequence has been finished according to sequence map criteria as follows. An attempt is made to resolve all sequencing problems, such as compressions and repeats, but not necessarily within known annotated human repeat sequence elements (e.g. Alu). Where the sequence is ambiguous, there is an annotation using the 'unsure'
                                                                                                                                                                                                                                                      The following abbreviations are used to associate primary accession numbers given in the feature table with their source databases:
Dms., EMBL: Sw., SWISSPROT; Tr.; TREMBL; Wp., WORMPEP: Information on the WORMPEP database can be found at http://www.sanger.ac.uk/Projects/C_elegans/wormpep This sequence chromosome 22, constructed by the Sanger Centre Chromosome 22 http://www.sanger.ac.uk/RBP/Otex/C_elegans/contre Chromosome 22 http://www.sanger.ac.uk/RBP/Chr22 RPI-302D9 is from the library RPCI-1 constructed at the Roswell Park Cancer Institute by the group of Pieter de Jong. For further details see http://bacpac.med.buffalo.edu/
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             This sequence is the entire insert of clone RP1-302D9 The true left end of clone CTA-482F2 is at 69682 in this sequence. The true right end of clone CTA-415G2 is at 55167 in this sequence. Location/Qualifiers
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"note-"Alux repeat: matches 1. 309 of consensus"
1653. 3928
"note-"MLTIE repeat: matches 136. 359 of consensus"
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note="MLT1E repeat: matches 116. .136 of consensus"
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hote="MLTIE repeat: matches 359. .568 of consensus"
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033. .1336
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/note="Alub repeat: matches 1, ,311 of consensus" 5369, .6485
//ote="Lz repeat: matches 1, .312 of consensus"
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Anote—"Alusp repeat: matches 1. .299 of consensus"
1450. .1583
Anote—"MIR repeat: matches 24. .160 of consensus"
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note="Alusq repeat: matches 2. 300 of consensus"
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note="THEIB repeat: matches 3. .364 of consensus"
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6647. .6685
/note="MADE1 repeat: matches 1.
6686. .6987
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'note="MER3 repeat: matches 1.
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/organism="Homo sapiens"
/db_xref="taxon:9606"
/chromosome="22"
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/clone_11b="RPCI-1"
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//octe="match: GSS: Em:AQ005063"
19251. .19719
//note="match: GSS: Em:B14179"
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horte-"Alusp repeat: matches 1. .313 of consensus"
2281. .23801
/note-"MER66-internal repeat: matches 1210. .2186 o
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23905. .23989
/note="MER66-internal repeat: matches 3017. .3102
                                                                                                     /note="MER66-internal repeat: matches 4548. .4919
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                      consensus"
18333. .18712
7note-"AluJb repeat: matches 1. .311
18713. .19133
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RP11,354H17, WORKING DRAFT
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primates; Catarrhini; Hominidae; Homo.
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Eukaryota; Metazoa; Chk
Mammalia; Eutherda; Pr:
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